Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER
No. 2014 - _____

SUBJECT: **Revised Rules and Regulations Governing the Generic Labeling Requirements of Pharmaceutical Products for Human Use**

I. RATIONALE

Article III, Section 7 of the 1987 Philippine Constitution declares that the State recognizes the right of the people to gain information on matters of public concern, such as those relating to health and health products.

Labels and labeling materials are the primary source of information for consumers. They provide useful information such as those dealing with the safe and effective use of a pharmaceutical product (e.g., indication(s), pharmacologic class and dosage), and information dealing with quality (e.g., manufacturing and expiration dates, registration number, and manufacturer).

The Food and Drug Administration (FDA), as the regulatory authority of the Philippines responsible for all matters pertaining to pharmaceutical products, has crafted several issuances to ensure that drug establishments provide the most accurate information relating to their products. In the course of the enforcement of these issuances, coupled with the advent of globalization and development of harmonization schemes of technical procedures and requirements applicable to the pharmaceutical industries in the ASEAN region, gaps in regulations have been identified, and the need for a more transparent and clear regulatory guideline pertaining to labels has been raised.

Hence, this Order is issued to rationalize the regulations on labeling of pharmaceutical products for human use, as well as to address the gaps and issues raised for the effective implementation of the declared policy.

II. DECLARATION OF POLICY

It is declared a policy of the State to protect and promote the right to health of the people and instill health consciousness among them, as provided under Article II, Section 15 of the 1987 Philippine Constitution. Furthermore, it is declared a policy of the State to protect consumers against hazards to health and safety, and to provide information to facilitate sound choice in the proper exercise of their rights as consumers.

In the implementation of the foregoing policy, the Department of Health, through the Food and Drug Administration, is mandated in accordance with the provisions of Section 5 (o) of Republic Act 9711, otherwise known as the "Food and Drug Administration Act of 2009," to prescribe standards, guidelines, and regulations with respect to information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities about health products.

III. OBJECTIVE

The objective of this Administrative Order is to rationalize the existing rules and regulations on generic labeling requirements of pharmaceutical products, consistent with the harmonized requirements of the ASEAN Member States; thus, providing a more updated and comprehensive guideline as a response to the needs of the pharmaceutical industry and the public.

IV. SCOPE

This Administrative Order shall apply to all manufacturers, traders and distributors (i.e. exporters, importers and wholesalers) of pharmaceutical products for human use, including herbal medicines and traditionally-used herbal products.

V. DEFINITION OF TERMS

For purposes of this Administrative Order, the following terms shall mean:

1. Active Moiety - the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

2. Active Pharmaceutical Ingredient (API) - a substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a therapeutically active compound (ingredient).
3. Adverse Drug Reaction (ADR) - a response to a medicine that is noxious and unintended, and which occurs at doses normally used in man.
4. Batch - a defined quantity of starting material, packaging material or product manufactured in a single or series of processes so that it can be expected to be homogeneous. (In the case of continuous manufacture, the batch must correspond to a defined fraction of production, characterized by its intended homogeneity; it may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch).
5. Batch Number - a distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records, and the certificates of analysis, etc.
6. Brand Name - the proprietary product name assigned to the product by the Marketing Authorization Holder (MAH).
7. Contraindication - a statement regarding the conditions wherein the use of the pharmaceutical product may cause harm to the patient.
8. Date of Manufacture - refers to the date (month and year) during which processing of the bulk product, from which the goods are to be filled, is completed.
9. Dosage - the quantity of a medicine given per administration.
10. Dosage Form - the pharmaceutical product type (e.g., tablet, capsule, solution, cream) that contains a drug substance generally, but not necessarily, in association with excipient(s).
11. Dosage Strength - may refer to:
    (a) the concentration of the known API in a given formulation stated in metric units
    (b) the potency of the known API expressed in terms of, for example, units by reference to a standard (potency is the specific ability or capacity of the product as indicated by the appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended to effect a given result(s)). This shall be stated in accordance with the potency requirements of the monograph of the product, as officially listed in USP, BP and EP, or any other official compendia recognized by FDA.
12. Excipient - an ingredient, added intentionally to the drug substance which should not have pharmacological properties in the quantity used.

13. Expiration Date - the date (i.e. month and year) placed on the label of a drug product designating the time prior to which a batch of the product is expected to remain within the approved shelf-life specification if stored under defined conditions. After the expiration date, there is no guarantee that the product will remain within the approved specifications and, therefore, it may be unsuitable for use and should not be used.
14. Formulation - the name, strength, and reference monograph of all APIs and/or excipients present in the pharmaceutical product.
15. Generic Class Name - the identification of a pharmaceutical product containing three or more APIs by its scientifically and internationally recognized name or by its official generic name as determined by FDA.
16. Generic Name - the identification of a pharmaceutical product by its scientifically and internationally recognized active pharmaceutical ingredient or by its official generic name as determined by FDA.
17. Indication - the FDA-approved clinical use of a pharmaceutical product based on substantial, scientifically supported evidence of its safety and efficacy in the given dosage form.
18. Label - the written, printed or graphic matter on any pharmaceutical product, its immediate container, tag, literature or other suitable material affixed thereto for the purpose of giving information as to the identity, components, ingredients, attributes, directions for use, specifications and such other information as may be required by law or regulation.
19. Labeling Materials - label on the immediate container, and the other printed materials that are made available with the pharmaceutical product at the time of purchase and/or when the product is used, such as the outer wrapper cartons, SPC/package insert/leaflet accompanying the product, which provide the accurate and necessary detailed information for the identification and proper use of the product.
20. Large Volume Parenterals – injectable preparations with a volume more than 100mL.
21. Lot Number - any distinctive combination of letters and/or numbers assigned to a particular lot, herein defined as a portion of a batch.
22. Manufacturer - an establishment engaged in any and all operations involved in the production of health products as well as the final release of the finished product, with the end view of its storage, sale or distribution; provided, that the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies.
23. Marketing Authorization (MA) - an official document issued by the competent drug regulatory authority (DRA) for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy, and

quality, and containing, *inter alia*: the name of the product; the pharmaceutical dosage form; the quantitative formula (including excipients) per unit dose; the shelf-life and storage condition(s); and packaging characteristics; specific information on which authorization is based (e.g., "The product(s) must conform with all the details provided in the application and as modified in subsequent correspondence."); the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization. In the Philippines, the MA is in the form of a Certificate of Product Registration (CPR).

24. Marketing Authorization Holder (MAH) - the company or corporate or legal entity in the field of pharmaceuticals in whose name the MA for a pharmaceutical product has been granted. This party is responsible for all aspects of the product, including quality and compliance with the conditions of the MA. The authorized holder must be subjected to legislation in the country that issued the MA, which normally means being physically located in that country. In the Philippines, the MAH may either be a manufacturer, trader, or distributor (exporter, importer or wholesaler).
25. Mode of Administration - the manner and site where the pharmaceutical product is to be introduced into or applied on the body.
26. Net Content - the total amount/quantity/number of the dosage form in a certain container of a pharmaceutical product expressed in metric system.
27. New Chemical Entity (NCE) - new chemical or biological API not previously authorized for marketing for any pharmaceutical use in the country in question.
28. Over-the-Counter (OTC) Drugs - pharmaceutical products or drug preparations that can be dispensed even without the written order of a licensed physician or dentist.
29. Pack Size - refers to the quantity of dosage form in the final packaging (excluding the shipping carton) of a pharmaceutical product bearing the required labeling information.
30. Package Insert (PI) - the document defining information that is supplied with a prescription pharmaceutical product by the MAH.
31. Patient Information Leaflet (PIL) - the document defining information intended for the patient that is supplied with over-the-counter (OTC) preparations and household remedies by the MAH.
32. Pharmacologic Category - refers to the classification of the pharmaceutical product based on its therapeutic action as specified in the product registration.

33. Precautions - the instruction and the special care required in the use of the pharmaceutical product to avoid undesired effects and to ensure its safe and effective use.
34. Prescription Pharmaceutical Products - pharmaceutical products that are to be dispensed only upon written order or prescription of a duly licensed physician or dentist for the management or treatment of a condition or a diagnosed disease of man.
35. Primary Label - refers to the label on the primary packaging material of a pharmaceutical product.
36. Product Name - the name (i.e. Generic Name and Brand Name, if any) of the pharmaceutical product as registered in FDA.
37. Product Description - refers to the complete organoleptic description of the finished pharmaceutical product.
38. Registration Number - a combination of letters/numbers assigned to a particular pharmaceutical product by FDA as proof of registration.
39. Shelf-life - the time period during which a drug product is expected to remain within the approved specifications, provided that it is stored under the conditions defined in the label.
40. Small containers - are pharmaceutical packaging materials that hold less than or equal to 5 mL volume or 5 g weight, which include:
    (a) ampoules, vials, and nebules of small volume parenterals;
    (b) packaging materials for ophthalmic, otic, and nasal liquid preparations;
    (c) jars and tubes for semi-solid preparations; and
    (d) any other packaging material of the same capacity.
41. Small Volume Parenterals – injectable preparations with a volume of 100mL and below.
42. Storage Condition(s) - the acceptable specified range temperature, humidity, and other environmental factors within which optimal stability of the pharmaceutical product is ensured based on laboratory data.
43. Summary of Product Characteristics (SPC) - the product information as approved by the DRA. It also serves as the source of information for health personnel as well as for consumer information on labels and leaflets of pharmaceutical products advertisement for control of advertising.
    A Company Core Data Sheet (CCDS) approved by the DRA may also be considered.
44. Undesirable Effects - also known as adverse events, refer to untoward medical occurrence that may present during treatment with a drug product but which does not necessarily have a causal relationship with this treatment.

45. Warnings - statements regarding the occurrence of potential hazards and undesirable effects associated with the use of the pharmaceutical product and the limitation of its use.

VI. GENERAL REQUIREMENTS

The following are the minimum mandatory information that shall appear in the labeling materials accompanying a pharmaceutical product:

1. Product Name
2. Dosage Form and Strength
3. Pharmacologic Category
4. Formulation/Composition
5. Indication(s)
6. Dosage and Mode of Administration
7. Contraindication(s), Precaution(s), Warning(s) (if applicable)
8. Interactions
9. Undesirable Effects
10. Overdose and Treatment
11. Storage Condition(s)
12. Net Content or Pack Size
13. Name and Address of MAH
14. Name and Address of Manufacturer
15. For prescription pharmaceutical products, the Rx Symbol and Caution Statement
16. ADR Reporting Statement
17. Registration Number
18. Batch Number and Lot Number (if any)
19. Expiration Date and Date of Manufacture

All information required to appear on the label shall be (a) written in English and/or Filipino and (b) readable with normal vision without straining. The color contrast, position and spacing of the printed matters on the label must be taken into consideration in complying with labeling requirements.

For all NCEs, biotechnological products, and prescription generic products and herbal products, a package insert shall be submitted; for all household remedies, over-the-counter drug and herbal medicines, and traditionally-used herbal products, a patient information leaflet shall be submitted. The SPC shall be the basis of the submitted PI for NCEs and biotechnological products.

In lieu of package insert or patient information leaflet, the foregoing information may be printed directly on the reverse side or inner panel of the outer packaging material or inner carton; provided, that the product is intended to be sold or dispensed together with such packaging material or inner carton.

For products intended to be sold without any product information sheet, the minimum mandatory information shall be required to be reflected on the primary label.

The specific information required for each labeling material is indicated under Annex A.

VII. SPECIFIC REQUIREMENTS

A. *Product Name*

1. the product name shall indicate the generic name and the brand name (if any) of the pharmaceutical product;
2. the generic name shall be as the active moiety based on the International Non-proprietary Name (INN), and consistent with the dosage strength indicated; for pro-drugs, the generic name shall be the INN of the prodrug itself and not its active chemical (metabolite) form;
3. the generic name shall appear prominently with an outline box, with the generic name's prominence over the other information being clearly and distinctly readable by normal vision as may be determined by common visual sense;
4. for herbal medicines and traditionally-used herbal products, the generic name shall be the botanical origin or as recognized by FDA;
5. if a product is identified by a brand name together with its generic name, the generic name enclosed in an outline box shall in all cases appear immediately above the brand name; for narrative texts (whether in the unit carton, primary label or insert), the brand name shall in all cases be preceded by the generic name and enclosed in parenthesis or brackets;
6. for products with multiple APIs, the product name shall indicate all of the APIs, enumerated in the order of decreasing pharmacologic activity and placed inside the box in either of the given format:
   Ex.:

Ferrous Sulfate
Folic Acid

Brand Name

Ferrous Sulfate / Folic Acid

Brand Name

Ferrous Sulfate + Folic Acid

Brand Name

If the APIs have more or less similar pharmacologic activity, they shall be enumerated in the order of decreasing potency and strength; provided, that if there exists a single approved name for fixed-dose combination (e.g., Cotrimoxazole for the standard formulation Sulfamethoxazole / Trimethoprim), the single approved name shall be used; provided further, that if there is no single approved name but there exist a generic class name (e.g., Multivitamins for multi-vitamin containing preparations, as approved by FDA), the generic class name shall be used.

The individual components of the single approved name and generic class name shall be enumerated under Formulation.

B. *Dosage Form and Strength*

1. The label shall specify the (a) dosage form of the product such as tablet, capsule, suspension, ointment, etc., (b) the specific delivery system, if any such as modified release, and (c) specific mode of administration, if any and appropriate, such as vaginal/rectal suppository, etc., as approved by FDA. If there is no qualifier for tablets, it is understood as an oral, uncoated, immediate release tablet.
2. The label shall specify the dosage strength of the product which shall be expressed in metric units reduced to lowest terms and in the number of the largest unit specified (e.g., 500mcg, not 0.5mg).
3. FDA, as deemed necessary and appropriate, shall allow the strength of certain dosage forms to be expressed as percentage.
4. For products with multiple APIs, the dosage strength shall be stated in accordance with the generic name indicated: for multiple APIs, the individual strengths shall be indicated, separated by a slash sign (/); if a single approved name is used, the dosage strength shall be indicated as the sum.

   Ex.:

Piperacillin Sodium / Tazobactam Sodium

Brand Name

4 g / 500 mg Powder for Injection (IV)

Piperacillin Sodium + Tazobactam Sodium

Brand Name

4 g / 500 mg Powder for Injection (IV)

Piperacillin Sodium
Tazobactam Sodium

Brand Name

4 g / 500 mg Powder for Injection (IV)

Cotrimoxazole

Brand Name

960 mg Tablet

C. *Pharmacologic Category*

The pharmacologic category shall be as determined by FDA, taking into consideration current acceptable standards for therapeutic categories.

D. *Formulation/Composition*

1. The label shall state the name and strength of all APIs present per unit dose of the product, which shall be indicated by their generic names, arranged in decreasing potency.
2. The name of the API shall be stated in full (including salts and esters, if any) and correlated to the active moiety, when applicable. The name of the API shall be in accordance with its International Non-Proprietary Name (INN); for herbal medicines and traditionally-used herbal products, the official Philippine Pharmacopeia name shall be used, or as determined by FDA.
3. The reference monograph used for the analysis of the finished pharmaceutical product shall be indicated immediately after the API, unless a non-official method is used; for multiple APIs, it shall be indicated after the first API.

Each tablet contains:
Sodium Ascorbate, USP.....562.5 mg
(equivalent to Ascorbic Acid 500 mg)

Each tablet contains:
Calcium Carbonate, BP.....750mg
(equivalent to elemental Calcium 300 mg)

Each capsule contains:
Amoxicillin (as Trihydrate), USP.....500mg

Each vial contains:
Omeprazole (as Sodium) 40mg

Each tablet contains:
Sulfamethoxazole, USP.....800mg
Trimethoprim.....160mg

4. Alcohol, when present in the product must also be indicated, expressed as a percentage (%). The name "alcohol" without qualification shall mean ethyl alcohol.
5. The coloring agent and other excipients used in the manufacture of the product that may cause hypersensitivity and/or other adverse drug reactions shall also be indicated, with the amount expressed in the same manner as the API.
6. Any preservative and/or antimicrobial agents present in the formulation shall also be included, with the amount expressed in the same manner as the API.

E. *Indication(s)*

The indication(s) stated in the labeling materials shall include only the FDA-approved clinical use(s) of the pharmaceutical product.

F. *Dosage and Mode of Administration*

1. The label shall contain full information on the product's recommended dosage, including the (a) initial or loading dose, (b) optimal use or usual dose, (c) frequency interval, (d) duration of treatment, (e) dosage adjustment, and other pertinent aspects of drug therapy, if applicable.
2. Relevant information regarding dilution, reconstitution, preparation, and administration should also be included (such as "Shake well before use" for suspensions, "Do not Crush" for tablets with special delivery system, etc.) in all labeling materials. The label shall include a description of the reconstituted preparation.
3. Separate directions for use by special populations, adults and children must be stated. If the product is not recommended for children, the dosage shall be clearly identified as "Adult dose", or any statement to that effect.

G. *Contraindication(s), Precaution(s), Warning(s)*

1. The label shall contain full information regarding the contraindication(s) of a pharmaceutical product, as well as the precaution(s) to be observed in its administration and use.
2. The label shall include warning statements, as required and/or specified by FDA (e.g., "Flammable," "For external use only," "Keep out of reach of

children"). Other specific additional instructions shall be issued by FDA in appropriate regulations.

3. Where the contents of a container are to be used on one occasion only, the label shall include the statement, "Single use only", "Single dose", "Use only once", "Discard any remaining portion", or any statement to that effect.

H. *Interactions*

The label shall include drug-drug, drug-food, drug-laboratory testing interactions, as well as other relevant interactions, if applicable.

I. *Undesirable Effects*

The label shall include detailed information on adverse event for a drug product.

J. *Overdose and Treatment*

The label shall include signs and symptoms of overdose, as well as possible treatment.

K. *Storage Condition(s)*

1. The label shall indicate appropriate storage condition(s) and special instructions for handling of the pharmaceutical product.
2. Special labeling instructions shall be added for pharmaceutical products with the following properties:

Properties	Special labeling instructions
Cannot tolerate refrigeration	"Do not refrigerate or freeze"
Cannot tolerate freezing	"Do not freeze"
Light-sensitive	"Protect from light"
Cannot tolerate excessive heat, e.g., suppositories	"Store and transport not above 30 °C"
Hygroscopic	"Store in dry conditions"

L. *Pack Size or Net Content*

1. The **unit carton** shall indicate the pack size of the pharmaceutical product expressed in terms of the number of units in the pack or the volume of each unit, e.g., 60 mL (for liquids), 10 blister packs x 10 tablets (for tablets), 100 tablets, 12 sachets x 5 g, etc.; Provided, that in case of pharmaceutical products for reconstitution, the pack size shall reflect the volume of the product as reconstituted.
2. For the **primary label excluding blisters and foil strips**, the net content of the product, stating the total amount/quantity/number of the dosage

form in a given container shall be expressed in metric units, e.g., 60 mL (for liquids), 5 g (for sachets), etc.

M. *Name and Address of Marketing Authorization Holder*

The label shall state the name and full address of the MAH for the pharmaceutical product.

N. *Name and Address of Manufacturer*

The label shall state the name of the manufacturer and full address of the specific manufacturing site for the pharmaceutical product.

O. *Rx Symbol and Caution Statement*

1. The labeling materials of prescription pharmaceutical products shall always include the Rx symbol, which shall be prominently displayed. The Rx symbol may be allowed to be over-printed or superimposed, provided, that such will not result in the obliteration by or being rendered less legible than other required labeling information.
2. The caution statement, "**Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.**" shall always be included in the **package insert, unit carton**, **primary label except blister pack, foil strip, and small containers** of prescription pharmaceutical products. In addition, for products classified as Dangerous Drug as per Republic Act No. 9165, the caution statement shall be followed as specified by the Philippine Drug Enforcement Agency (PDEA).

P. *ADR Reporting Statement*

1. For the unit carton and primary label except blister pack, foil strip, and small containers, the statement "**For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph**" should appear.
2. For the product information sheet, a statement instructing the patient to seek medical attention immediately at the first sign of any adverse drug reaction.

   In addition, the company may include a reporting statement for their own pharmacovigilance system.

Q. *Registration Number*

The label shall indicate the registration number assigned by FDA to the product, which is denoted by a combination of letters/numbers.

R. *Batch Number and Lot Number*

The label shall indicate the product's batch number; provided, that if the entire batch is marketed by one drug establishment, only the batch number shall be indicated. However, if a batch is divided into lots marketed by different drug establishments, the lot number and corresponding batch number shall be indicated.

S. *Expiration Date and Date of Manufacture*

1. The label shall bear the month and year of the product's manufacture and expiration either in letters/words and numbers, or in numbers alone; if expressed in numbers alone, the year shall be stated completely in order to distinguish it from the month; and if the day is specified, the month shall be spelled out, as shown below:
   (a) June 2007 or Jun 2007
   (b) 06/2007
   (c) 03 June 2007 or 03 Jun 2007
2. Unless a certain day of the month is specified, the last day of the stated month shall be deemed as the date of the product's expiration/manufacturing date.
3. For products reconstituted prior to use and those which can be administered multiple times (e.g., suspensions), the label shall include the period of guaranteed safety, efficacy, and quality of the reconstituted preparation/after first opening at a given storage condition(s).

VIII. SPECIAL LABELING INSTRUCTIONS

In addition to the minimum mandatory requirements mentioned, the following shall be required to appear on the label of specific product types:

A. *Parenterals*

For parenteral products, the following additional information shall be required:

1. For all labeling materials, in addition to the API(s), the name of all excipients and their amounts shall appear in the Formulation.
2. A statement of the recommended mode of administration such as "IV", "IM" or "SC", etc., as the case may be.
3. Where the product consists of a concentrated solution for injection, a direction not to administer the solution undiluted and a direction to dilute the solution with the specified diluent to the appropriate volume before use shall be stated.

B. *Fluid Replacement and Dialysis Solution Products*

1. For fluid replacement and dialysis solution products which follow the standard formulations contained in the current edition of the official compendium, the nomenclature to be adopted as the generic class name shall be determined by FDA.
2. For fluid replacement and dialysis solutions not included in any official compendia, FDA shall determine the generic class name.
3. Directly below the generic class name but still inside the generic outline box are the individual components with the corresponding mEq/L or mmol/L enumerated in the order of decreasing pharmacologic activity.
4. Where one or more substances are amino acids and/or proteins, the total amount of nitrogen in the nominal volume of fluid in the container shall be reflected.
5. The nominal osmolality, such as "hypotonic" or "hypertonic"; and the nominal pH range of the solution shall be indicated.

C. *Products for External Use*

For products that are intended for external use, the statement "For External Use Only" shall appear on all labeling materials, rendered in capital letters against a red background or printed in red font.

D. *Multivitamin/Mineral/Herbal Products with Standard Formulations and Non-vitamin/mineral/herbal Components*

Multivitamins, consisting of at least three vitamins, and minerals, consisting of at least three mineral ingredients, shall have the following additional requirements:

1. The generic name adopted for multivitamin-containing products shall be "Multivitamins"; for multi-mineral-containing products the official name shall be "Minerals".
2. For multivitamin and/or multi-mineral preparations containing at least three herbal ingredients, the generic class name of the herbal ingredients shall be "Herbs".
3. For multivitamin products with individual non-vitamin components (i.e. mineral or herbal ingredient), or multi-mineral products with individual non-mineral components (i.e. vitamin or herbal ingredient), or multi-herbal products with individual non-herbal components (i.e. vitamin or mineral ingredient) the term "Multivitamins" or "Minerals" or "Herbs", respectively, shall first be stated, followed by the generic name of the specific additional individual components, as shown below:

Ex.

Multivitamins + Iron

Multivitamins + Irons + *Panax ginseng*

Minerals + Ascorbic Acid + *Panax ginseng*

The unit content of each vitamin, mineral, and/or herbal ingredient present shall no longer be required to be indicated in the generic box, but rather shall be reflected under Formulation.

E. *Drugs under Maximum Drug Retail Price (MDRP) Control*

On the label of the minimum pack of drugs listed under Section 1 of Executive Order No. 821 and other drugs as determined by the Secretary of Health, the following statement shall be required to appear in red background or red font:

Ex.

UNDER DRUG PRICE REGULATION
RETAIL PRICE NOT TO EXCEED *(price)*

UNDER DRUG PRICE REGULATION
RETAIL PRICE NOT TO EXCEED *(price)*

F. *Unique Global Product Identification Number*

The existing rules and regulations for unique product identification number (Global Trade Item Number) shall be followed.

G. *Reproductive Health Products*

The product information included for reproductive health (RH) products shall be the PIL. The PIL shall be written in English and Filipino, and/or local dialect.

H. *Generic Drug Products with Proven Interchangeability*

On the unit carton and primary label except blister pack, foil strip, and small containers of generic drug products with proven interchangeability, either of the following statement shall appear:

This product has the same therapeutic efficacy as
any other generic product of the same name

This product has the same therapeutic efficacy as the innovator product of the same generic name

The Department of Health (DOH) and FDA may, from time to time, prescribe special labeling requirements for specific products.

IX. EXEMPTIONS

The requisites provided in this Administrative Order shall not apply to the following cases:

1. Drug products manufactured for export;
2. Veterinary drug products;
3. If the container or primary pack containing the product is enclosed in a transparent covering and the particulars which are required to be set on the label on the container or primary pack are clearly visible through transparent covering, the transparent covering is exempted;
4. Products that are compounded by a pharmacist in accordance with the individual prescription of a medical practitioner or dentist for immediate use;
5. Investigational drugs, i.e. new chemical or structural modification of a tried and tested or established drug proposed to be used for a specific therapeutic indication(s);
6. Foreign donations of pharmaceutical products;
7. Products that require special handling (e.g., pre-filled syringes, products that require cold-chain management); and
8. Low volume of importation.

A Generic Labeling Exemption (GLE) application shall be concurrently submitted by applicant companies with their application for pharmaceutical product registration, except for certain situations as promulgated by FDA. If granted, FDA shall issue a GLE certificate with a corresponding validity and number. The Registration Number assigned by FDA must be reflected on the label of the pharmaceutical product.

X. SANCTIONS

Any violation of this Administrative Order consistent with Republic Act No. 3720 and Republic Act No. 9711 and its implementing rules and regulations shall be a ground for filing of appropriate administrative charges and/or imposition of administrative sanctions such as, but not limited to, imposition of

fines, suspension, cancellation or revocation of any license, permit or registration issued by FDA.

XI. REPEALING AND SEPARABILITY CLAUSE

A.O. 55 s. 1988, A.O. 85 s. 1990, A.O. 99 s. 1990 and their implementing guidelines, A.O. 109 s. 1969, A.O. 126 s. 1970, A.O. 64 s. 1989, as well as other provisions in existing administrative issuances, bureau circulars and memoranda inconsistent with this Administrative Order are hereby withdrawn, repealed and revoked accordingly.

If any provision in this Administrative Order, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Administrative shall not be affected.

XII. TRANSITORY PROVISION

All registered pharmaceutical products shall be required to submit the revised labeling materials compliant with this Administrative Order upon renewal of their MA.

Reasonable exhaustion period shall be given to registered products subject to renewal within one (1) year of approval of this Administrative Order.

XIII. EFFECTIVITY

This Order shall take effect after fifteen (15) days following its publication in two (2) newspapers of national circulation and upon filing to the University of the Philippines Law Center-Office of the National Administrative Register.

ENRIQUE T. ONA, MD
Secretary of Health